DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12 FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Barry J. Cadden, Owner

FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	697 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

1. On 10/02/2012, we observed approximately eighty-three (83) vials out of a bin containing 321 vials of methylprednisolone acetate (preservative free) 80mg/mL from Lot #08102012@51 (shipped to customers between 8/17/12 – 9/25/12 per firm distribution data), a sterile injectable drug, to contain what appeared to be greenish black foreign matter. Seventeen (17) vials from the same bin of methylprednisolone acetate (preservative free) 80mg/mL were observed to contain what appeared to be white filamentous material.

The sterility sample taken by the firm consisting of one 5ml vial of bulk formulated methylprednisolone acetate (preservative free) from lot 08102012@51 resulted in a sterile result (lab analysis started 8/14/12 and reported 8/28/12). However, the FDA analysis of FDA Sample #693965, consisting of methylprednisolone acetate (preservative free) 80mg/mL, 1mL filled vials, from Lot #08102012@51 collected from the firm, confirmed the presence of viable microbial growth in 50/50 vials tested. One vial examined microscopically showed fungal morphological features.

2. Although the formula worksheets state the raw materials are sterile, the Pharmacy Director stated that the firm uses non sterile active pharmaceutical ingredients (APIs) and raw materials, with the exception of sterile water for injection, to formulate injectable suspensions including but not limited to preservative free methylprednisolone acetate and triamcinolone. During the inspection, we observed that the labeling for the methylprednisolone API and additional raw materials did not indicate that they were sterile. Samples were collected for analysis of the non-sterile API and 3 additional raw materials used in the formulation of methylprednisolone acetate. The firm provided no documentation or evidence to support that the steam autoclave cycle used to sterilize suspensions formulated using non-sterile API and raw materials is effective.

3. The firm's environmental monitoring program yielded the following microbial isolates (bacteria and mold) within Clean Room 1 and Clean Room 2, used for the production of sterile drug products, between January 2012 and September 2012. Firm personnel stated that the firm shuts off the air conditioning from 8:00 pm to 5:30 am nightly in the Clean Room.

Table #1: Surface Samples from ISO 6 (Class 1,000) Rooms
Alert: 3 CFU Action: 5+ CFU

Location	Result Bacteria	Result Mold	Date
Main Clean Room			
CRBin1 (polymyxin under station 1)	0	1	2/16/12
4 FLR (near hood 5)	10*	2*	2/23/12
2 FLR (near hood 3)	3	1	3/8/12

BLACK LINE ON ORIGINAL - NOT A REDACTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	10/26/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180	10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12
Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Barry J. Cadden, Owner

FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	697 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Location	Result Bacteria	Result Mold	Date
4 FLR (near hood 5)	2	2	3/15/12
Table 2	0	1 mold (¾ of plate)*	3/29/12
1 FLR (near hood 1)	One hair with growth around it		3/29/12
4 FLR (near hood 5)	OG*	0	4/5/12
CRBin1(inside big uline bin with omnipaque 240)	1	1	6/13/12
3 FLR (near horiz hoods)	OG*	0	6/13/12
3 FLR (near horiz hoods)	1	2	6/28/12
CRBin2 (front of tetracaine Hcl powder container)	0	OG mold*	7/5/12
Pass thru	0	1 small mold	7/26/12

Note: (*) indicates result over action level; OG indicates over growth

Table #2: Surface Samples of ISO 7 (Class 10,000) Rooms
Alert: 5 CFU Action: 7+ CFU

Location	Result Bacteria	Result Mold	Date
Gown Room (Clean Room 1)			
8 FLR (GR/near hooks)	23*	0	2/16/12
GRmisc2 (vent arms)	13*	1*	2/16/12
GRmisc2 (empty plastic bag in empty bin)	19*	0	2/23/12
GRmisc1 (vent arms behind hand washer)	27*	0	2/23/12
7 FLR (gown room/entrance)	2*	11*	2/23/12
8 FLR (gown room/near hooks)	11*	4*	2/23/12
7 FLR (gown room/entrance)	0	1	3/1/12
WallGR2 (windowsill side to MR)	18*	0	3/1/12
8 FLR (gown room/near hooks)	12*	0	3/1/12
GRmisc2 (vent grids)	16*	2*	3/1/12
7 FLR (gown room/entrance)	3	2	3/8/12
8 FLR (gown room/near hooks)	3	2	3/8/12
7 FLR (gown room/entrance)	3	3	3/15/12
8 FLR (gown room/near hooks)	0	2	3/15/12
8 FLR (gown room/near hooks)	16*	0	3/29/12

BLACK LINE ON ORIGINAL - NOT A REDACTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Thomas W Nerney, Investigator	Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	11/1/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12 FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Barry J. Cadden, Owner

FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	697 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Location	Result Bacteria	Result Mold	Date
GRmisc2 (floor under barrel against wall)	11*	0	3/29/12
8 FLR (gown room/near hooks)	10*	0	4/5/12
7 FLR (gown room/entrance)	0	1	4/5/12
GRmisc1 (rubber flap over wheel of rack)	9*	0	4/12/12
WallGR1 (window sill side to middle room)	9*	0	4/12/12
GRmisc1 (top of rack with bouffants)	12*	0	5/10/12
7 FLR (GR/entrance)	2	1	5/31/12
8 FLR (GR/near hooks)	19*	0	5/ 31/12
8 FLR (GR/near hooks)	0	13*	6/28/12
7 FLR (GR entrance)	3	3	6/28/12
GRmisc1 (bottom of bootie bin)	¾ of plate OG*	1*	7/26/12
GRmisc2 (bottom of mask bin)	plate ¾ overgrown*	0	7/26/12
8 FLR (GR/near hooks)	9*	0	7/26/12
GRmisc2 (front of 7-7.7 glove bin)	OG*	1*	8/2/12
GRmisc2 (loose bootie bin)	0	Plate ½ mold*	8/23/12
Middle Room (Clean Room 1)			
5 FLR (near crimp bench)	0	1	2/23/12
6 FLR (near sink bench)	0	3	2/23/12
6 FLR (near sink bench)	2*	11*	3/15/12
MRmisc1 (dh20 gallon)	1	1	5/10/12
Gown Room (Clean Room 2)			
Gown Room Flr	OG*	0	1/26/12
Gown Room Flr	0	1	3/1/12
Gown Room Flr	9*	0	8/9/12
Prep Room (Clean Room 2)			
Prep Room Flr	1	1	2/2/12
Misc #2 PR (top of radio)	0	1	2/7/12
Misc: PR (Calcium chloride bin)	1	1	4/4/12
Prep Room Flr	15*	2*	6/13/12

Note: (*) indicates result over action level; OG indicates over growth

BLACK LINES ON ORIGINAL - NOT A REDACTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	[signature]	Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	1/26/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12 FEI NUMBER 3003623877
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	
TO: Barry J. Cadden, Owner	
FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	697 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Table #3: Surface Samples of ISO 8 (Class 100,000) Rooms
Alert: 8 CFU Action: 10+ CFU

Location	Result Bacteria	Result Mold	Date
Prep Room (Clean Room 1)	[redacted]		
Misc. Prep room samples (shopping cart handle)	0	OG with mold*	1/6/12
Misc. Prep room samples (metal cart)	1	1	1/26/12
PR (carriage w/blue handle w/scratch marks)	3	1	2/2/12
PR (carriage w/blue handle w/x)	4	1	2/2/12
PR (outside of barrel)	16*	2*	3/1/12
9 FLR (PR) (near entrance)	1	7	3/8/12
PR (blue tamper evident caps, bin)	4	3	3/15/12
PRmisc2 (inside plastic cover to clear plastic bags)	OG*	0	4/5/12
9 FLR prep room (near entrance)	¼ plate OG*	0	4/5/12
10 FLR (PR) (under 2nd rack)	3	1	4/12/12
PR MISC 2 (top of lid of white container under rack)	1	1	5/24/12
10 FLR (PR) (back of room area)	OG*	0	5/24/12
10 FLR (PR) (back of room area)	0	3	5/31/12
9 FLR (PR) (entrance area)	OG*	0	6/15/12
10 FLR (PR) (back of room area)	20*	0	6/15/12
10 FLR (PR) (back of room area)	12*	0	6/28/12
9 FLR (PR) entrance area	4*	15*	6/28/12

Note: (*) indicates result over action level; OG indicates over growth

BLACK LINE ON ORIGINAL - NOT A REDACTION

Table #4: Air Sampling of ISO 6 (Class 1,000) Rooms

Location	Result Bacteria	Result Mold	Date
Middle Room (Clean Room 2)	[redacted]		
Middle room	0	1 big mold	5/29/12

BLACK LINE ON ORIGINAL - NOT A REDACTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	[signatures]	Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	11/26/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180	10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12
Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Barry J. Cadden, Owner

FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	697 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Table #5: Air Sampling of ISO 7 (Class 10,000) Rooms
Alert: 5 CFU Action: 8+ CFU

Location	Result Bacteria	Result Mold	Date
Gown Room (Clean Room 1)			
Gown room	29*	1*	5/31/12
Gown room	11*	1*	6/28/12
Middle Room (Clean Room 1)			
Crimp Station	3	1	2/23/12
Prep Room (Clean Room 2)			
Prep room	0	1	5/2/12
Gown Room (Clean Room 2)			
Gown room	7*	3*	8/9/12

Note: (*) indicates result over action level

BLACK LINES ON ORIGINAL - NOT A REDACTION

Table #6: Surface and Air Sampling of ISO 5 (Class 100) Clean Room 2
No Action/Alert Levels specified by firm for ISO 5 (Class 100) areas.

Location	Sample Type	Result Bacteria	Result Mold	Date
Table 1 (near Horiz L & R hoods)	Surface	0	3	1/26/12
Table 1 (near Horiz L & R hoods)	Surface	1	1	5/2/12
Between Horiz L & Horiz R	Air	1	1	7/25/12

There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacteria and mold) from the facility.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Thomas W. Nerney, Investigator	Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	10/26/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12 FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Barry J. Cadden, Owner

FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	697 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

4. The environmental monitoring procedure requires sampling via personnel touch plates taken upon completion of sterile compounding and prior to cleaning. Records from January thru September 2012 for Clean Room 1 and Clean Room 2 showed the following results inside production hoods:

Table #1: Clean Room 1 and Clean Room 2 Facility Personnel Touch Plates

Date	Isolates	Location	Product
1/3/12	OG with bacteria	Horizontal 1 (Clean Room 1)	Avastin
4/12/12	OG with bacteria	IT/Hood 3 (Clean Room 1)	Product not documented
6/15/12	1 bacteria, 1 mold	Horizontal 2A (Clean Room 1)	Ropiv/Ketor/Epi
6/21/12	2 bacteria	Horizontal R (Clean Room 2)	Product not documented
7/2/12	½ plate OG with bacteria	Horizontal L (Clean Room 2)	Product not documented
7/19/12	1 bacteria, 2 molds	Horizontal 2C (Clean Room 1)	Mafenide Acetate
7/31/12	2 bacteria	Horizontal 2A (Clean Room 1)	KCl/Lido/D5W
8/16/12	2 bacteria	Hood 3 (glovebox) (Clean Room 1)	Ace 20%, Ped Atropine

Note: OG indicates over growth

These results were not investigated and there was no identification of the isolates. There were no product impact assessments performed for any sterile products that were made in the hoods or gloveboxes on the days the samples were taken. In addition, the firm has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products.

5. The conditions listed below were identified during the inspection in areas used for the preparation, filling, and/or storage of sterile drugs products.

- On 10/04/2012, we observed condensation and what appeared to be tarnished discoloration on the interior surfaces (e.g. chamber) of the "[redacted (b)(4)] autoclave", located in the firm's Middle Room (ISO 7). This autoclave is used for the steam sterilization of formulated bulk drug suspensions, including preservative free formulations of methylprednisolone and triamcinolone, which are intended for injection. Of note, this is the final sterilization step in the process for these products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	[signature] Investigator Thomas Nerney, Investigator	Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	10/26/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12
	FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Barry J. Cadden, Owner

FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	697 Waverly Street
CITY, STATE AND ZIP CODE Framingham, MA 01702	TYPE OF ESTABLISHMENT INSPECTED Compounding Pharmacy

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

- On 10/04/2012, we observed greenish yellow discoloration lining the interior surface of the viewing lens within the "Inside" autoclave, located in the firm's Middle Room (ISO 7). This is one of two tabletop autoclaves used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation of sterile drug products

- On 10/04/2012, we observed what appeared to be tarnished discoloration on the interior surfaces (e.g. chamber and trays) of the "Outside" autoclave located in the firm's Middle Room (ISO 7). Moreover, condensation was observed along the interior surfaces of the "Outside" autoclave to collect in a pool at the base of the chamber. This is one of two tabletop autoclaves used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation of sterile drug products.

- The firm is abutted to the rear and along the left parking area by a recycling facility that handles such materials as mattresses and plastics. On 10/02/2012, the area was observed to include large equipment (e.g. excavators and freight trucks) producing airborne particulates (e.g. dust). Rooftop units serving the firm's HVAC system were estimated to be located approximately 100 feet from the recycling facility.

- On 10/04/2012, we observed what appeared to be dark particulate and white, filamentous substances covering the louvers of an HVAC return located behind the "(b) (4) autoclave", located in the firm's Middle Room (ISO 7). This autoclave is used for the steam sterilization of formulated bulk drug suspensions, including preservative free formulations of methylprednisolone and triamcinolone, which are intended for injection.

- On 10/02/2012 and 10/04/2012, we observed yellow residue lining the rear return of Weigh Station 2 Hood and greenish residue lining the rear return of Weigh Station 3 Hood, both located in the firm's ISO 6 Clean Room. The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

- On 10/04/2012, we observed greenish residue covering the surface of the (b) (4) ceiling, exposed to the (b) (4) filter above, within Weigh Station 3 Hood located in the firm's ISO 6 Clean Room. The firm uses Weigh Station Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

- On 10/04/2012, we observed what appeared to be tarnished discoloration on the interior surfaces (e.g. chamber and trays) of the (b) (4) located in the firm's Prep Room (ISO 8). This (b) (4) is used to sterilize equipment (e.g. beakers, spatulas, and spoons) used in the formulation of sterile drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	10/26/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New England District Office 1 Montvale Ave, Stoneham, MA 02180 Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12
	FEI NUMBER 3003623877

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Barry J. Cadden, Owner

FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	697 Waverly Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

- On 10/04/2012, a boiler installed within approximately 30 feet of the entrance to the Prep Room (ISO 8) was observed to be leaking water into puddles. Moreover, wet floor surfaces around the boiler appeared to be soiled with thick white debris and thick black, granular material. Gaps were observed between sliding doors, located at the transition between the Prep Room (ISO 8) and the warehouse, despite being fully closed. This room is used for the preparation of equipment and includes the (b) (4)

- On 10/02/2012, the tacky mat located within the entrance of the Prep Room (ISO 8), at the transition to the warehouse, was observed to be brown and soiled. This room is used for the preparation of equipment and includes the (b) (4) (b) (4)

- On 10/04/2012, we observed cloudy discoloration on the (b) (4) barrier (b) (4), facing the ISO 6 Clean Room, and metal surfaces within the "Pass Thru," installed within the wall of the ISO 6 Clean Room. Moreover, the metal ledge, within the ISO 6 Clean Room, was observed to contain reddish-brown and cloudy substances. The firm utilizes the ISO 6 Clean Room to formulate and fill sterile preparations, including methylprednisolone.

- On 10/04/2012, we observed what appeared to be dark, hair-like discoloration along the gasket and crevices located at the bottom edge of the closed pass through installed within the wall of the ISO 6 Clean Room. The firm utilizes the ISO 6 Clean Room to formulate and fill sterile preparations, including methylprednisolone.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nemey, Investigator Debra M. Emerson, Investigator	11/12/12

Drugs

Multistate outbreak of fungal meningitis and other infections

Laboratory Testing and Results

[12-12-2012] FDA and CDC have identified bacterial and/or fungal contamination in unopened vials of betamethasone, cardioplegia, and triamcinolone solutions distributed and recalled from NECC. These include bacteria known as *Bacillus*, and fungal species including *Aspergillus tubingensis, Aspergillus fumigatus, Cladosporium* species,and *Penicillium* species. Although rare, some of the identified *Bacillus* species can be human pathogens. Some of the fungal organisms identified, particularly *Aspergillus fumigatus*, are known to cause disease in humans. It is not known how product contamination with these organisms could affect patients clinically. See CDC's Advice for Clinicians[1].

CDC and FDA Laboratory-Confirmed Organisms from Product Samples

Laboratory-Confirmed Organisms from Product Samples Associated with NECC Recalled Lots of Betamethasone, Cardioplegia, and Triamcinolone Solutions

Medication	Lot Number	Bacterial and Fungal Contamination
Betamethasone 6 mg/mL injectable –5 mL per vial	08202012@141	*Paenibacillus pabuli/amolyticus, Bacillus idriensis, Bacillus flexus, Bacillus simplex, Lysinibacillus* sp., *Bacillus niacini, Kocuria rosea, Bacillus lentus*
Betamethasone 6 mg/mL injectable –5 mL per vial	07032012@22	*Bacillus niabensis, Bacillus circulans*
Betamethasone 12 mg/mL injectable – 5 mL per vial	07302012@52	*Bacillus lentus, Bacillus circulans, Bacillus niabensis, Paenibacillus barengoltzii/timonensis*
Betamethasone 6mg/mL injectable – 5 mL per vial	08202012@44	*Bacillus lentus, Bacillus firmus, Bacillus pumilus*
Betamethasone 6 mg/mL injectable – 5 mL per vial	08152012@84	*Penicillium* sp., *Cladosporium* sp.
Triamcinolone 40mg/mL injectable – 1 mL per vial	06062012@6	*Bacillus lentus, Bacillus circulans, Bacillus niabensis, Bacillus nealsonii, Bacillus subtilis group, Bacillus firmus*
Triamcinolone 40 mg/mL injectable – 2 mL per vial	08172012@60	*Aspergillus tubingensis, Penicillium* sp.
Triamcinolone 40mg/mL injectable – 10 mL per vial	08242012@2	*Aspergillus fumigatus*
Cardioplegia solution 265.5 mL per bag	09242012@55	*Bacillus halmapalus/horikoshii, Brevibacillus choshinensis*

Related Information

- FDA Form 483 for New England Compounding Center (PDF - 1.7MB)[2]
- Archive of Updates on Fungal Meningitis Outbreak[3]
- List of Recalled Products Related to Fungal Meningitis Outbreak[4]
- Meningitis Outbreak: Voriconazole and Liposomal Amphotericin B Availability Information[5]

Page Last Updated: 09/06/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. http://www.cdc.gov/medicationsafety/recalls/necc/#advice

2. /downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM325980.pdf
3. /Drugs/DrugSafety/FungalMeningitis/ucm325037.htm
4. /Drugs/DrugSafety/ucm322752.htm
5. /Drugs/DrugSafety/DrugShortages/ucm323947.htm

Drugs

Questions and Answers on Fungal Meningitis Outbreak

en Español[1]

Q1. What is FDA's role in the investigation?

A1. FDA was been working closely with CDC, several state health departments, and the Massachusetts Board of Pharmacy to investigate the scope and cause of the outbreak of fungal meningitis. FDA inspectors in the New England District Office, in cooperation with the Massachusetts Board of Registration in Pharmacy, have been conducting an inspection of the New England Compounding Center. FDA has confirmed the presence of a fungal contaminant in multiple sealed vials of methylprednisolone acetate collected from NECC, and is in the process of conducting additional testing to confirm the species of the fungus.

Q2. Is New England Compounding Center still producing sterile injectable products?

A2. No. The firm voluntarily ceased all operations and surrendered its license to the Massachusetts Board o Registration in Pharmacy on October 3, 2012. NECC has also announced a voluntary recall of all of their products.

Q3. What should health care providers do to protect their patients from the threat of potential contamination?

A3. Although the investigation into the source of the outbreak is still ongoing, if you have purchased a product from NECC, we are advising you not to use it at this time. Please see the CDC website[2] for additional information. See Q9 regarding advice to health care providers related to the additional injectable products, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, or a cardioplegic solution purchased from or produced by NECC.

Q4. Are there other FDA approved epidural steroid injections that can be used?

A4. There are FDA approved versions of methylprednisolone acetate injection on the market, available with or without preservatives. The FDA-approved products are not approved for epidural administration.

Q5. Does FDA anticipate a shortage of epidural steroid injection drug supply?

A5. No. FDA's drug shortage office has confirmed that NECC's voluntary shutdown will not affect the nationwide supply of methylprednisolone acetate.

Additional Patient Notification Advisory

Q6. What led FDA to take this action?

A6: As a result of FDA, CDC, and state health departments' ongoing investigation of contamination at the New England Compounding Center's (NECC) Framingham, Massachusetts facility, we have learned that two patients may have infections associated with other possibly contaminated NECC products. While the investigation of these patients is ongoing, and there may be other explanations for their infections, out of an abundance of caution, we are issuing new guidance for providers to contact their patients for whom they administered an injectable product, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, or a cardioplegic solution purchased from or produced by NECC after May 21, 2012.

With regard to the two patients who are being evaluated, we can provide the following information. One patient, identified through active surveillance, is under investigation for possible meningitis potentially associated with epidural injection of an additional NECC product, triamcinolone acetonide. Triamcinolone acetonide is a type of steroid injectable product made by NECC. FDA-approved triamcinolone acetonide is approved for intra-articular (within a joint) or soft tissue injection. The cases of meningitis identified to date have all been associated with methylprednisolone acetate, another similar steroid injectable product.

In addition, one heart transplant patient with *Aspergillus fumigatus* infection who was administered NECC cardioplegic solution during surgery hase been reported. Investigation of these patients is ongoing, and,

there may be other explanations for their *Aspergillus* infection. Cardioplegic solution is used to induce cardiac muscle paralysis during open heart surgery to prevent injury to the heart.

At this time, no patients are under investigation in connection with any NECC-produced ophthalmic drug that is injectable or used in conjunction with eye surgery, but FDA believes this class of products could present potentially similar risks of infection because of concerns about sterility.

Q7: Does FDA believe these products are contaminated with the same fungus as the methylprednisolone acetate?

A7: At this point in the investigation, FDA analysis of triamcinolone acetonide collected from the health car facility that reported the new meningitis case is being cultured, and we will release results when available.

Q8: Does FDA believe all products compounded by NECC are at risk?

8A: The investigation is ongoing. On October 4, we urged providers not to use any products made at NECC. At this point in FDA's investigation, the sterility of any injectable drugs, including ophthalmic drugs that are injectable or used in conjunction with eye surgery, and cardioplegic solutions produced by NECC are of significant concern.

Q9: What should HCPs and patients do who were given these products?

A9: The FDA has previously issued guidance for medical professionals that all products distributed by NECC should be retained, secured, and withheld from use. NECC has voluntarily recalled all products that it has distributed. Based on new information, FDA advises that if, after May 21, 2012, a health care professional administered to a patient an injectable product, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, or a cardioplegic solution purchased from or produced by NECC, the healthcare professional should follow up with those patients and make sure the patients are aware of the signs and symptoms of infection and instruct them to contact their health care provider immediately if they have any of these symptoms. Products from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo that can be accessed here[3].

At this time, FDA is not advising health care professionals to contact patients who have been administered lower risk NECC products such as topicals (for example, lotions, creams, eyedrops not used in conjunction with surgery) and suppositories.

Patients who believe they received an injection or other product compounded by NECC after May 21, 2012 should remain vigilant for the signs and symptoms of infection, including meningitis. The signs and symptom of meningitis include fever, headache, stiff neck, nausea and vomiting, photophobia (sensitivity to light) an altered mental status. Symptoms for other possible infections may include fever; swelling, increasing pain, redness, warmth at injection site; visual changes, pain, redness or discharge from the eye; chest pain, or drainage from the surgical site (infection within the chest). Patients should contact their healthcare provider if they have any of these signs or symptoms.

Q10: FDA is advising doctors to contact any of the patients to whom they have administered an NECC injectable drug, including ophthalmic products or cardioplegic solutions, after May 21, 2012. How many products does that encompass?

A10: NECC has provided a list of products that they have produced and distributed, which can be found and accessed here [HTML[4] | PDF[5]]. There are about 1200 products on that list. A large percentage of these products are injectables, including ophthalmic products that are injectable or used in conjunction wit eye surgery and cardioplegic solutions. FDA is working with NECC to produce a specific list of injectables, including ophthalmic products and cardioplegic solutions, and will post that as soon as possible.

Q11: What steps should health care professionals take to communicate with patients?

A11: FDA recognizes that some health care professionals may receive a high volume of calls from patients or be concerned about having to notify many patients as a result of FDA's recommendation. FDA defers to the clinical judgment of healthcare professionals to decide the appropriate communications mode, whether it is email, phone (including voicemails), letter, or otherwise. Face-to-face communication with patients is not necessary to notify patients.

Q12: Are the FDA-approved versions of triamcinolone acetonide contraindicated for epidural administration?

A12: FDA-approved triamcinolone acetonide is approved for intra-articular (within a joint) or soft tissue injection. The FDA-approved triamcinolone acetonide is not approved for spinal injections.

Q13: What should patients do if they are diagnosed with meningitis or joint infections associated with the use of contaminated NECC products?

A13: Patients who have been diagnosed with meningitis or joint infections should consult with their healthcare providers about the appropriate treatment regimen, including the risks and benefits of all treatment options. CDC has published interim treatment guidance for adult patients diagnosed with central nervous system and/or parameningeal infections as well as septic arthritis associated with injection of potentially contaminated steroid products from NECC. These recommendations include treatment with an antifungal drug called voriconazole. CDC also advises providers to consider giving another antifungal drug, liposomal amphotericin B, in addition to voriconazole, to treat patients with severe disease and patients who do not respond to voriconazole alone. Providers can refer to CDC's website at http://www.cdc.gov/hai/outbreaks/clinicians/index.html[6] for the most up-to-date CDC treatment recommendations.

Q14: In your MedWatch message, FDA advised healthcare professionals to follow-up with patients who have been administered an injectable product shipped by NECC on or after May 21, 2012, including an ophthalmic drug that is injectable or used in conjunction with eye surgery, or a cardioplegic solution. Are there other clinical settings where FDA suggests healthcare professionals follow-up with patients?

A14: In addition to injectable NECC products, ophthalmic drugs used in conjunction with eye surgery, and cardioplegic solution shipped on or after May 21, 2012, there are other potential uses of NECC products where FDA advises healthcare professionals to use their clinical judgment in deciding when to follow-up wit patients. Other clinical conditions that warrant follow-up with patients who received NECC products on or after May 21, 2012, include but are not limited to:

- Infusion into a sterile body site
- Irrigation of a sterile body site (e.g., bladder, skin laceration, intra-operative)
- Inhalation
- Application to an eye with a corneal abrasion
- Transplant of an organ (e.g., organ transplant)

Q15: What advice is available for patients who may have NECC products in their implantable pump

A15. FDA is aware of the possibility that products made and distributed by the New England Compounding Pharmacy (NECC) may have been intended for use in implantable pumps for a variety of patient populations. These products were recalled by NECC earlier this month. In some cases, the nature of the implant may make compliance with the recall notice impractical or unsafe. FDA continues to evaluate information as it becomes available, but at this time does not have sufficient data to determine the degree of risk or concern associated with any continued exposure to these products. FDA urges health care providers and clinics that purchased NECC products for use in implantable pumps to maintain a heightened vigilance for signs of infections in those patients or their pumps, and to reach out to those patients to discuss medical options available to them as appropriate.

Related Information

- Multistate outbreak of fungal meningitis and other infections[7]
- Multi-State Meningitis Outbreak (CDC)[8]
- CDC Health Advisory[9]

Page Last Updated: 11/01/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue

Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. /Drugs/DrugSafety/ucm324323.htm
2. http://emergency.cdc.gov/HAN/han00327.asp
3. http://www.neccrx.com/necc-logo.gif
4. http://www.fda.gov/Safety/Recalls/ucm322979.htm
5. http://www.fda.gov/downloads/Safety/Recalls/UCM322970.pdf
6. http://www.cdc.gov/hai/outbreaks/clinicians/index.html
7. /Drugs/DrugSafety/FungalMeningitis/default.htm
8. http://www.cdc.gov/hai/outbreaks/meningitis.html
9. http://emergency.cdc.gov/HAN/han00327.asp

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

Multistate Outbreak of Fungal Meningitis and Other Infections –Healthcare Facilities

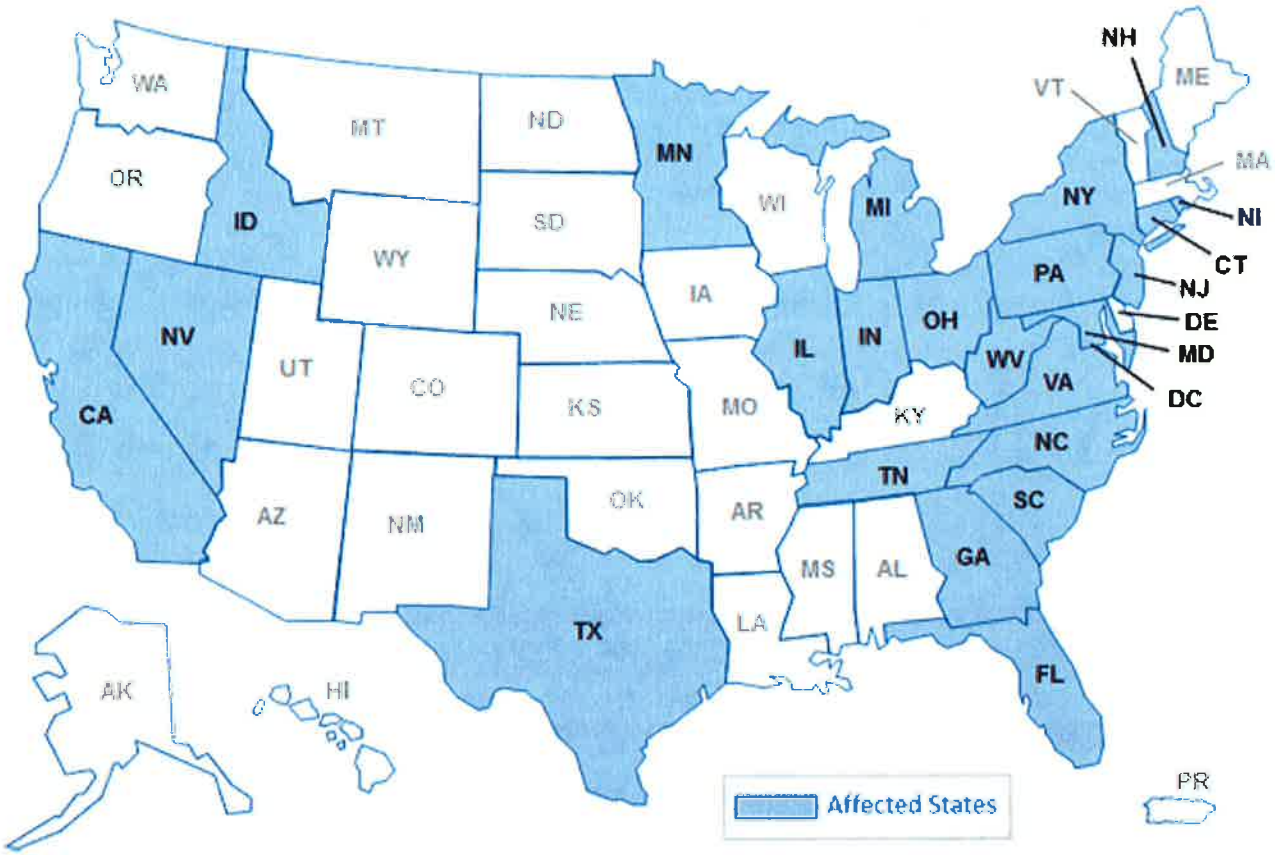
Although **further updates to the case counts are not anticipated at this time,** patients affected by tainted steroid injections from the New England Compounding Center continue to receive treatment for their infections and clinicians should continue to monitor patient recovery.

CDC will update the relevant clinical materials on this page if there is a significant development in clinical disease management. All relevant materials for patients (/hai/outbreaks/patients/index.html) and clinicians (/hai/outbreaks/clinicians/index.html) concerning the multistate outbreak of fungal meningitis and other infections are located on this page.

Map of Healthcare Facilities that Received Three Recalled Lots of Methlyprednisolone Acetate (MPA) from NECC associated with the Multistate Outbreak of Fungal Meningitis and other Infections

OCTOBER 23, 2013 FURTHER UPDATES TO THE CASE COUNTS ARE NOT ANTICIPATED AT THIS TIME.

See table (#facilities_table) for a complete list of health care facilities.



Recalled Lots of MPA

Lot #05212012@68, BUD 11/17/2012
Lot #06292012@26, BUD 12/26/2012
Lot #08102012@51, BUD 2/6/2013

List of Healthcare Facilities that Received Lots of Methylprednisolone Acetate Recalled from NECC associated with the Multistate Outbreak of Fungal Meningitis and other Infections

Facility Name	Phone Number	City	State
California			
CYPRESS SURGERY CENTER	559-740-4094	VISALIA	CA
ENCINO OUTPATIENT SURGICENTER	818-986-1037	ENCINO	CA
UKIAH VALLEY MEDICAL CENTER	707-463-7345	UKIAH	CA
UNIVERSAL PAIN MANAGEMENT	661-267-6876 x166	PALMDALE	CA
Connecticut			
INTERVENTIONAL SPINE AND SPORTS MED	203-598-7246	MIDDLEBURY	CT
Florida			
FLORIDA PAIN CLINIC	352-237-5906	OCALA	FL
INTERVENTIONAL REHABILITATION CENTER	850-484-8800	PENSACOLA	FL
MARION PAIN MANAGEMENT CENTER	352-622-1845	OCALA	FL
NORTH COUNTY SURGICENTER	561-626-6446	PALM BEACH GARDENS	FL
ORLANDO CENTER FOR OUTPATIENT SURGERY	407-426-8331	ORLANDO	FL
PAIN CONSULTANTS OF WEST FLORIDA	850-494-0000	PENSACOLA	FL
SURGERY CENTER OF OCALA	352-237-5906	OCALA	FL
SURGICAL PARK CENTER	305-271-9100 x226	MIAMI	FL
Georgia			
FORSYTH STREET AMBULATORY SURGURY CENTER	478-749-1610	MACON	GA
Idaho			
PAIN SPECIALISTS OF IDAHO	208-522-7246	IDAHO FALLS	ID
WALTER KNOX MEMORIAL HOSPITAL	208-365-3561 x3342	EMMETT	ID
Illinois			
APAC CENTERS FOR PAIN MANAGEMENT	708-483-7007	WESTCHESTER	IL
APAC CENTERS FOR PAIN MANAGEMENT	773-935-2760	CHICAGO	IL
THOREK MEMORIAL HOSPITAL	773-975-6734	CHICAGO	IL
Indiana			

AMBULATORY CARE CENTER LLC	812-475-1800	EVANSVILLE	IN
FORT WAYNE PHYSICAL MEDICINE	260-436-9337	FORT WAYNE	IN
OSMC OUTPATIENT SURGERY CENTER	574-266-4173	ELKHART	IN
SOUTH BEND CLINIC	574-237-9372	SOUTH BEND	IN
UNION HOSPITAL	812-238-4964	TERRE HAUTE	IN
WELLSPRING	812-376-0700	COLUMBUS	IN
Maryland			
BALTIMORE PAIN MANAGEMENT	410-682-5040	BALTIMORE	MD
BERLIN INTERVENTIONAL PAIN MANAGEMENT	410-641-3759	BERLIN	MD
BOX HILL SURGERY CENTER	410-877-8141	ABINGDON	MD
GREENSPRING SURGERY CENTER	410-653-0077	BALTIMORE	MD
HARFORD COUNTY ASC, LLC	410-538-7000	EDGEWOOD	MD
PAIN MEDICINE SPECIALISTS	410-825-6945	TOWSON	MD
SURGCENTER OF BEL AIR	410-638-5523	BEL AIR	MD
Michigan			
MICHIGAN NEUROSURGICAL INSTITUTE	810-606-7112	GRAND BLANC	MI
MICHIGAN PAIN SPECIALISTS	734-995-7246	BRIGHTON	MI
NEUROMUSCULAR & REHABILITATION	231-935-0860	TRAVERSE CITY	MI
SOUTHEAST MICHIGAN SURGICAL HOSPITAL	586-427-1000	WARREN	MI
Minnesota			
MAPS-EDINA MEDICAL PAIN CLINIC	763-537-6000	MINNEAPOLIS	MN
MAPS-MEDICAL ADVANCED PAIN	763-537-6000	FRIDLEY	MN
MEDICAL ADVANCED PAIN SPECIALISTS	763-537-6000 x238	SHAKOPEE	MN
MEDICAL ADVANCED PAIN SPECIALISTS.	763-537-6000	MAPLE GROVE	MN
MINNESOTA SURGERY CENTER	763-767-7139	EDINA	MN
MINNESOTA SURGERY CENTER-	763-537-6000	MAPLE GROVE	MN
North Carolina			
HIGH POINT SURGERY	336-878-6048	HIGH POINT	NC
NORTH CAROLINA ORTHOPAEDIC CLINIC	919-403-5148	DURHAM	NC
SURGERY CENTER OF WILSON	252-237-5649	WILSON	NC
New Hampshire			
DR. O'CONNELL'S PAIN CARE CENTER	603-335-5070	MERRIMACK	NH
DR. O'CONNELL'S PAIN CARE CENTERS, INC	603-692-3166	SOMERSWORTH	NH
New Jersey			
CENTRAL JERSEY ORTHOPEDICS SPECIALISTS PC	908-561-2122	SOUTH PLAINFIELD	NJ
EDISON SURGICAL CENTER	732-452-0123	EDISON	NJ
IF PAIN ASSOCIATES / ISAIAH FLORENCE	201-287-1100	TEANECK	NJ
PREMIER ORTHOPEDICS SURG. ASSOC., LLC	856-690-1750	VINELAND	NJ

COMPREHENSIVE PAIN MANAGEMENT	973-796-5216	SPARTA	NJ
SOUTH JERSEY HEALTH CARE	856-363-1558	ELMER	NJ
SOUTH JERSEY HEALTHCARE	856-641-7557	VINELAND	NJ
Nevada**			
SAHARA SURGERY CENTER	702-362-7874	LAS VEGAS	NV
New York			
BUTANI, SUNIL H., PHYSICIAN PC	516-747-5042	MINEOLA	NY
OBOSA MEDICAL SERVICES	914-530-2323	MOUNT VERNON	NY
ROCHESTER BRAIN AND SPINE	585-334-5560	ROCHESTER	NY
Ohio			
BKC PAIN SPECIALISTS, LLC	740-387-7246	MARION	OH
CINCINNATI PAIN MANAGEMENT	513-891-0022	CINCINNATI	OH
MARION PAIN CLINIC	740-375-0200	MARION	OH
ORTHO-SPINE REHABILITATION CENTER, INC.	614-793-8817	DUBLIN	OH
Pennsylvania			
ALLEGHENY PAIN MANAGEMENT	814-940-2000	ALTOONA	PA
SOUTH HILLS PAIN & REHAB ASSOCIATES	412-469-7722	JEFFERSON HILLS	PA
Rhode Island			
NEW ENGLAND ANESTHESIOLOGY (NEA)	401-490-7530	WARWICK	RI
OCEAN STATE PAIN MANAGEMENT	401-766-7700	WOONSOCKET	RI
OCEAN STATE PAIN MANAGEMENT	401-884-6070	EAST GREENWICH	RI
South Carolina			
INTERVENE MD	843-216-4844	MOUNT PLEASANT	SC
Tennessee			
PCA PAIN CARE CENTER	865-835-5196	OAK RIDGE	TN
SPECIALTY SURGERY CENTER	931-484-2500 x125	CROSSVILLE	TN
ST. THOMAS OUTPATIENT NEUROSURGICAL	615-341-3425	NASHVILLE	TN
Texas			
DALLAS BACK PAIN MANAGEMENT	214-445-5077	DALLAS	TX
HARRIS METHODIST SOUTHLAKE CENTER	817-748-8778	SOUTHLAKE	TX
Virginia			
INSIGHT IMAGING-ROANOKE	540-581-0882	ROANOKE	VA
NEW RIVER VALLEY SURGERY CENTER	540-639-5888	CHRISTIANSBURG	VA
West Virginia			
PARS INTERVENTIONAL PAIN	304-865-7277	PARKERSBURG	WV

** All vials of methylprednisolone acetate that were sent to Nevada were recalled prior to use.

Page last reviewed: October 23, 2013
Page last updated: October 23, 2013
Content source: Centers for Disease Control and Prevention

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Division of Healthcare Quality Promotion (DHQP)

Centers for Disease Control and Prevention 1600 Clifton Rd. Atlanta, GA 30333, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - Contact CDC–INFO